

The Department of Health and Human Services
Meeting of the Secretary's Advisory Committee on Human Research Protections (SACHRP)
Tuesday, March 12, 2013 – Wednesday, March 13, 2013
Hubert H. Humphrey Building, Room 800
AGENDA

Tuesday, March 12, 2013

CLOSED SESSION

8:30 am – 8:45 am

Welcome: Opening Remarks

Jeffrey R. Botkin, M.D.
SACHRP Chair

Jerry Menikoff, M.D., J.D.
Director, OHRP

8:45 am- 9:15 am

Ethics Training

9:15 am- 10:15

FACA Training

10:15 am – 10:30 am

BREAK

OPEN SESSION

10:30 am – 10:45 am

Welcome and Opening Remarks

Jeffrey R. Botkin, M.D.
SACHRP Chair

Jerry Menikoff, M.D., J.D.
Director, OHRP

10:45 am – 11:15 am

Welcome and Remarks

Howard Koh, M.D., M.P.H.
Assistant Secretary for Health
U.S. Department of Health and Human Services

11:15 am- 12:30 pm

SACHRP Background and the Rulemaking Process
HHS Staff

12:30 pm – 1:30 pm

LUNCH

1:30 pm- 2:30 pm

Discussion of SACHRP Member's Priorities

Jeffrey Botkin, M.D.
SACHRP Chair

2:30 pm – 3:15 pm

HIPAA/HITECH Rulemaking Changes

Christina Heide, J.D.
Senior Health Information Privacy Policy Specialist
Office for Civil Rights

3:15 pm - 4:30 pm

Subcommittee on Harmonization (SOH)

David Forster, J.D., SOH Co-chair
Mark Barnes, J.D., SOH Co-chair

4:30 pm – 4:45 pm

Public Comment

4:45 pm – 5:00 pm

Wrap-up Discussion and Adjourn

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Opening Remarks

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Director, OHRP

8:45 am- 11:00 am

Focus: Improving the Informed Consent Process

Jeremy Sugarman, MD, MPH, MA
Harvey M. Meyerhoff Professor of Bioethics and Medicine
Johns Hopkins Berman Institute of Bioethics

Heather H. Pierce, JD, MPH
Senior Director
Science Policy and Regulatory Counsel
Association of American Medical Colleges

Jeanne M. Adler, RN, MPH, CCRP
Clinical Investigations Branch
Cancer Therapy Evaluation Program
National Cancer Institute

Jeffrey S. Abrams, M.D.
Associate Director, Cancer Therapy Evaluation Program
Acting Director for Clinical Research
Associate Director of the Cancer Therapy Evaluation Program,
National Cancer Institute

11:00 am – 11:15 am

BREAK

11:15 am- 12:30 pm

Subpart A Subcommittee (SAS)

Daniel K. Nelson, M.S., CIP, SAS Co-chair
David Borasky, M.P.H., CIP, SAS Co-chair

12:30 pm- 1:30 pm

LUNCH

1:30 pm – 2:15 pm

Subpart A Subcommittee (SAS) ...Continued

2:15 pm- 3:30 pm

Human Subjects Research and the Internet

Elizabeth Buchanan, Ph.D.
Endowed Chair in Ethics
Director of the Center for Applied Ethics
University of Wisconsin-Stout

Dean R. Gallant, A.B.
Assistant Dean for Research Policy and Administration
Harvard University

3:30 pm – 3:45 pm

Public Comment

3:45 pm – 4:00 pm

Wrap-up Discussion and Adjourn